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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,790	09/19/2001	Paul Laurence Cervi	13533-002001/F/USP81213	2047
26161	7590	05/28/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/955,790	Applicant(s) CERVI, PAUL LAURENCE	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 22-27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-27, 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 7-11, 16 and 19 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 6, 12-15, 17, 18 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 1 is objected to because of the following informalities: Claim 1 recites a “needle” and a “single hollow tube”, which are both coupled to the handle, and are apparently two separate elements. It appears that the needle should “further comprise a single hollow tube” to eliminate any possible confusion. Appropriate correction is required.
2. Claim 29 is objected to because of the following informalities: In line 25, the phrase “said orifice of cannula handle” should read as “said orifice of said cannula handle” to be grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5, 7-11, 16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lalor et al (GB 2164277 A).

Lalor et al disclose a bone drill and further disclose a handle (11) for inserting the needle into the bone marrow tissue (See Figure 1); the needle comprises a single hollow tube (10) configured for both cutting and receiving a bone marrow tissue sample, coupled to the handle (11) (See Figure 1); the tube (10) having a tube bore defining a tissue-receiving space for the bone marrow sample, a substantially rigid tip, an outer

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wall configured to contact the bone marrow tissue, the outer wall being provided with an abrading formation (12) extending in an axial direction along the tube (10) to abrade the bone marrow tissue (See Figure 1; and lines 76-89); the abrading formation (12) comprises at least one slot (13) cut into the outer wall, the slot (13) having a sharp edge (See Figures 1 and 2); the abrading formation comprises a plurality of slots (13) spaced circumferentially about the bore (See Figure 1); the slot (13) extends in an axial direction at least one centimeter from the tip (See Figure 1); the tube (10) further comprises a sample detacher at the tip to assist in detaching a base portion of the tissue sample from adjoining tissue (See lines 76-89); the sample detacher comprises a detacher slot (13) cut into a wall of the tip (See lines 76-89); the sample detacher extends through the wall of the tip (See Figure 1 and lines 76-89); the sample detacher comprises a plurality of sample detacher slots (13) circumferentially about the tip (See Figure 1 and lines 76-89); the tube bore extends through the handle (11) (See lines 76-89); and the tube (10) has a sharpened beveled tip (See Figure 1).

Even though Lalor et al discloses the use of the bone drill for obtaining bone samples and not bone marrow samples, the structure of the device allows the drill to penetrate the cortical and trabecular bone structures to obtain a bone biopsy. Since the device is capable of drilling through the cortical and trabecular bone structures, it is also capable of obtaining a bone marrow sample once the bone drill has passed through the trabecular bone.

Allowable Subject Matter

5. Claims 3, 4, 6, 12-15, 17, 18 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: Claims 22-27 are contain allowable subject matter since no prior art could be found teaching or suggesting a coupling member detachably connected to the tissue sampling member, for coupling the needle to a rotary drive, as claimed in Claim 22; and Claims 29 and 30 are allowable since no prior art could be found teaching or suggesting the connector attachment having a shaft affixed to its proximal end, the knob and shaft being sized to fit within the orifice of the cannula handle distally and the knob sized to fit an electric drill or electric screw driver proximally, as claimed in Claim 29. Claim 29 will be allowable once the above objection is overcome.

Response to Arguments

7. Applicant's arguments with respect to claims 1-19 and 31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BS



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